DEC 2 0 2013

K132652

5. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

DATE PREPARED	11/15/2013
APPLICANT	Sequent Medical, Inc. 11A Columbia Aliso Viejo, CA 92656 Tel: (949) 830-9600 Fax: (949) 830-9658
OFFICIAL CORRESPONDENT	Melanie Parravi 11A Columbia Aliso Viejo, CA 92656 melaniep@sequentmedical.com Tel: (949) 830-9600 x 130 Fax: (949) 830-9568
TRADE NAME	VIA™ Microcatheter
COMMON NAME	Continuous Flush catheter
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1210
PRODUCT CODES	DQY: Percutaneous Catheter KRA: Continuous Flush Catheter
PREDICATE DEVICES	Marksman Catheter (K091559) Excelsior XT-27 Microcatheter (K113778)
PRIOR SUBMISSION	There has been a prior submission for the subject device and approval was obtained under K123477 for peripheral and coronary indications
PURPOSE OF SUBMISSION	The purpose of this submission is to gain marketing clearance for an expansion of the Indications for Use to include use of the VIA™ and VIA™ PLUS Microcatheters in the neuro vasculature. The submission also requests clearance to extend the shelf life from 6 months to 1 year.

SUBSTANTIALLY EQUIVALENT TO:

The VIA™ Microcatheter is substantially equivalent to the previously cleared Marksman™ Catheter (K091559), Excelsior XT-27 Microcatheter (K113778) and VIA™ Microcatheter (K123477).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The VIA™ Microcatheter and VIA™ PLUS Microcatheter are designed to be introduced over a steerable guidewire into the vasculature. The physician inserts the catheter into the vein or artery through the skin (percutaneous) using a sheath or guidewire. The device can then be navigated to the treatment site. Navigation is aided by the coated surface of the catheter which assists with manipulation while in the vasculature. Throughout the procedure the physician can obtain the position of the catheter by the tip marker using fluoroscopic techniques. Interventional devices and infusion of diagnostic and therapeutic agents can be delivered through the lumen of the catheter to the treatment site.
The VIA™ Microcatheter is a sterile single lumen device with a single distal tip marker designed to aid the physician in accessing distal vasculature when used with a guide catheter and steerable guidewire. Variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The proximal end of the catheter incorporates a standard luer adapter to facilitate attachment of accessories. A single radiopaque marker positioned at the distal tip facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating which reduces friction during manipulation in the vessel. The inner lumen of the catheter has a PTFE liner which assists with delivery of interventional devices, such as an intraluminal flow diverter.

The VIA™ and VIA™ PLUS Microcatheter are available in effective lengths of 154 cm and 133 cm and inner diameters of 0.27 inches and 0.33 inches, respectively. For commercialization purposes the 0.027 inch diameter will be named the VIA™ Microcatheter and the 0.033 inch diameter will be named the VIA™ PLUS Microcatheter.

The VIA™ Microcatheter is presented in a tyvek pouch and is sterile, single-use only and non-pyrogenic.

Accessories: Each VIA™ Microcatheter is provided with a shaping mandrel to facilitate distal tip shaping.

INDICATIONS FOR USE:

The VIA™ Microcatheter is intended for the introduction of non-liquid interventional devices (such as stents/flow diverters) and infusion of diagnostic (such as contrast media), or therapeutic agents into the neuro, peripheral and coronary vasculature.

TECHNICAL CHARACTERISTICS:
The VIA™ Microcatheter incorporates variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over a selectively-placed guidewire. The inner lumen incorporates a PTFE liner to facilitate movement of devices through the catheter's lumen to the intended destination in the vasculature. The outer surface of the catheter is coated with a hydrophilic coating which reduces friction during manipulation in the vessel. The tip of the catheter can be steam-shaped by physician for proper adjustment to the anatomy prior to use.

PERFORMANCE DATA:

Device performance testing confirms that the VIA™ Microcatheter can be used according to its intended use. The VIA™ Microcatheter has been verified and validated according to Sequent Medical's procedures for product design and development. Performance testing included:

- Bench Testing
- Sterilization Validation
- Packaging and Shelf Life Testing
- Biocompatibility and Chemical Testing
- Simulated Use Testing in Animals

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate device (s) for its intended use in the introduction of non-liquid interventional devices, infusion of diagnostic and therapeutic agents into the neuro, coronary, and peripheral vasculature.

The information provided by Sequent Medical in this 510(k) application was found to be substantially equivalent to all the predicate devices, including the Marksman™ Catheter (K091559), the Excelsior XT-27 Microcatheter (K113778) and the VIA™ Microcatheter (K123477)

NONCLINICAL TESTS DISCUSSION:

The nonclinical tests included:

- Physical characteristics unique to the VIA Microcatheter, such as visual and dimensional tolerances, kink resistance, and catheter tip shape retention
- Safety features such as burst pressure, tensile force, and coating adhesion
- Functional characteristics such as navigation and track force in a worst-case model that incorporates two 360 degree loops, as well as interventional device retraction and catheter flow rate.

The following table lists the bench tests performed, the methodology/purpose of the test, the associated international standard (if applicable), and final results.

Test	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
Visual and Dimensional	Tests conformance to specified microcatheter dimensions and visual criteria.	ISO 10555-1:2009 Internal test method	Met performance specifications per standard and test method	Complete conformance to standard
Kink Resistance	Measures diameter at which microcatheter shaft sections and junctions will kink.	BS EN 13868:2002 Internal test method	Met performance specifications per standard and test method	Conformance to standard with the following deviations: Kink diameter determined based on mechanical kink (drop in compressive force) instead of 50% reduction in water flow. This method is appropriate as the Via is primarily used to deliver non-liquid devices.
Tip Buckling	Tests force required for tip to buckle.	Internal test method	Met performance specifications per test method	Complete conformance to Sequent TM
Tracking Force	Tests force required to advance an interventional device through the microcatheter lumen.	Internal test method	Met performance specifications per test method	Complete conformance to Sequent TM
Steam Shaping and Shape Retention	Tests that microcatheter can be steam shaped to a clinically relevant angle and can maintain a minimum % of the initial angle after simulated use.	Internal test method	Met performance specifications per test method	Complete conformance to Sequent TM
Shaft Tensile	Measures the ultimate tensile strength of all Pebax and Vestamid junctions along the length of the catheter shaft.	ISO 10555-1:2009 Internal test method	Met performance specifications per standard and test method	Complete conformance to standard
Hub-Shaft Tensile	Measures the ultimate tensile strength of the hub to shaft junction.	ISO 10555-1:2009 Internal test method	Met performance specifications per standard and test	Complete conformance to standard

Test	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
			method	
Burst	Measures peak pressure before microcatheter burst/liquid leakage.	ISO 10555-1:2009 Internal test method	Met performance specifications per standard and test method	Complete conformance to standard
Coating Friction and Coating Integrity	Measures the average peak coating friction/lubricity. Coating integrity uses dye to test that coating remains adhered to catheter after simulated use.	Harland Medical Systems Coating Friction and Dye Test Methods FDA Guidance Document, Class II Special Controls for PTCA Catheters (section 12) (Issued 2010)	Met performance specifications per standard and test method	Complete conformance to supplier test methods In line with FDA guidance document on coating integrity
Coating Adherence/ Particulate	Measures particulate generated from the hydrophilic coating on exterior of microcatheter, as well as particulate generated from advancing an interventional device through the inner lumen of the microcatheter.	Internal test method FDA Guidance Document, Non-Clinical Engineering Tests for Intravascular Stents and Associated Delivery Systems (section 12) (Issued 2010) FDA Guidance Document, Class II Special Controls	Met performance specifications per standard and test method	Complete conformance to Sequent TM In line with FDA guidance documents on particulate testing

Test	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
		for PTCA Catheters (section 13) (Issued 2010)		
Hub Performance	Tests hub liquid and air leakage, as well as that the hub can withstand adequate forces. Tests that the hub meets general requirements for conical fittings.	ISO 594-1:1986 ISO 594-2:1998 Internal test method	Met performance specifications per standard and test method	Conformance to standard with the following deviations: Used an alternative ISO 594-2:1998 fitting to test hubs for Separation Force and Unscrewing Torque. The fitting used was measured to have a minor diameter greater than called for in the standard. This was deemed as worst case for these tests, therefore acceptable to use. Only short term stress cracking was inspected for on hubs. ISO 594-2:1998 calls for inspection after 48 hours. Intended use of Via microcatheter only requires RHV or syringes to be connected for short durations during delivery of implant, therefore long term testing is not applicable.

Nonclinical testing demonstrated that the VIA™ and VIA™ PLUS Microcatheter can perform as intended, and demonstrated substantial equivalence to the predicate devices: Marksman™ Catheter (K091559), Excelsior XT-27 Microcatheter (K113778) and VIA™ Microcatheter (K123477).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison, bench testing, and simulated use testing demonstrate the substantial equivalence of the VIA™ Microcatheter to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Sequent Medical, Inc.
Ms. Melanie Parravi, Vice President
Quality Assurance and Regulatory Compliance
11A Columbia
Aliso Viejo, CA 92656

Re: K132652
Trade/Device Name: VIA and VIA PLUS Microcatheters
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, DQY
Dated: September 23, 2013
Received: September 24, 2013

Dear Ms. Parravi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132652

Device Name: VIA and VIA PLUS Microcatheter

Indications For Use:

The VIA™ Microcatheter is intended for the introduction of non-liquid interventional devices (such as stents/flow diverters) and infusion of diagnostic (such as contrast media), or therapeutic agents into the neuro, peripheral and coronary vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S